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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,539	04/18/2001	John M. Barker	1032-P02148US1	7584

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SUITE 720  
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EXAMINER	
MARMOR II, CHARLES ALAN	
ART UNIT	PAPER NUMBER
3736	

DATE MAILED: 12/03/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/837,539

Applicant(s)

BARKER ET AL.

Examiner

Charles A. Marmor, II

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1,2,5 and 8-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,5 and 8-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 April 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

### DETAILED ACTION

1. This Office Action is responsive to the Response to Office Action filed October 22, 2002. The examiner acknowledges the amendments to claims 1, 2, 5, and 8; the cancellation of claims 3, 4, 6 and 7; and the addition of new claims 9-20. Claims 1, 2, 5 and 8-20 are pending.

#### *Drawings*

The following objections to the drawings were made in the Office Action mailed June 14, 2002. The Response to Office Action filed October 22, 2002 was not responsive to these drawing objections:

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: “**240**” as described on page 18, lines 6-8 and 10. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference sign(s) not mentioned in the description: “**454**” as illustrated in Figures 15 and 16. A proposed drawing correction, corrected drawings, or amendment to the specification to add the reference sign(s) in the description, are required in reply to the Office

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action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to because in Figure 18 the uppermost occurrence of reference sign “492” apparently should be deleted. A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

#### ***Specification***

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

#### ***Claim Objections***

The following objections to the claims were made in the Office Action mailed June 14, 2002. The Response to Office Action filed October 22, 2002 was not responsive to these claim objections:

6. Claims 1 and 8 are objected to because of the following informalities: in line 6, --;-- apparently should be inserted after “element”. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 17 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17 and 19 recite the limitation "the shielded position" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim. There is no shielded position recited in the claims prior to this recitation.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 2, 5 and 8-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoon ('053). Yoon teaches a safety needle instrument having a triggered safety member. The Yoon instrument is a medical device including a hollow housing **328**; a needle **324** having a sharpened tip **330** projecting forwardly from the housing; a spring biasing element **354** biasing the needle rearwardly; a needle retainer **386,394** releasably retaining the needle against the rearward bias of the biasing element; and a flexible shield **371** fixedly attached to the housing, projecting

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forwardly from the housing. The shield is configured for insertion into a patient. The shield sheathes the needle such that in a projecting position the sharpened tip of the needle projects beyond the forward edge of the shield, and in a retracted position the sharpened tip is enclosed within the shield. The shield is substantially puncture resistant so that the axial force required to buckle the shield is less than the force necessary to puncture the shield with the needle in order to prevent inadvertent contact with the contaminated needle. A lock **374** for locking the needle in the retracted position; a connector **104** in fluid communication with the needle for attaching to a fluid device; and a stop **336** for limiting the displacement of the needle may also be provided.

In operation, the needle is inserted into the patient; the actuator **394** of the needle retainer is actuated such that the biasing element displaces the needle, so the needle is locked in a shielded position; and fluid is infused or blood is collected through the shielded needle by the fluid device connected to connector **104**.

### ***Double Patenting***

11. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

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12. Claims 1, 8, 11 and 15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16, 18, 22, 24 and 28 of U.S. Patent No. 6,398,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because both the instant application and the patent teach a medical device including a needle having a sharpened tip; a biasing element for biasing the needle rearwardly; a needle retainer releasably retaining the needle against the bias of the biasing element; a shield that is substantially incompressible axially; and a connector for attaching to a fluid device, where the needle has a projecting position and a retracted position. As such, the claims of the patent and the claims of the instant application recite the same structural elements of the medical device and differ only in the intended use of the respective medical devices. Since the claims of the patent “anticipate” the claims of the instant application, the claims are not patentably distinct.

13. Claims 5 and 20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 2, 7-9, 11 and 15 of U.S. Patent No. 6,398,743. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent recite all of the method steps of the method claimed in claims 5 and 20 of the instant application with additional steps for inserting a guide wire into the patient. Since the narrower claims of the patent “anticipate” the broader claims of the instant application, the claims are not patentably distinct.

***Response to Arguments***

14. Applicant's arguments with respect to claims 1-8 have been considered but are moot in view of the new ground(s) of rejection. Applicant argues that Song et al. is not directed to a safety device and that the injection tube of Song et al. does not provide any type of safety feature to protect the needle. Applicant further contends that Song et al. does not teach or suggest a shield that is substantially puncture resistant or retracting a needle into such a shield; a biasing element; or a needle retainer. These arguments are moot in view of the cancellation of claims 3, 4, 6 and 7 and the new grounds of rejection made hereinabove.

***Conclusion***

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Haughton et al. teach a catheter trocar retraction system. Botich et al. teach a catheter insertion device with a retractable needle.

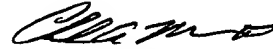
16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (703) 305-3521. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (703) 308-3130. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 308-0758 for After Final communications.



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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Charles A. Marmor, II  
Examiner  
Art Unit 3736

CAM  
December 1, 2002